

General

Guideline Title

ACR Appropriateness Criteria® lower extremity arterial revascularization–post-therapy imaging.

Bibliographic Source(s)

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Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report [Clinical Practice Guidelines We Can Trust](#).

■■■■= Poor ■■■= Fair ■■■= Good ■■■= Very Good ■■■= Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
■■■■	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement

	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
	Search Strategy
	Study Selection
	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
	Grading the Quality or Strength of Evidence
	Benefits and Harms of Recommendations
	Evidence Summary Supporting Recommendations
	Rating the Strength of Recommendations
	Specific and Unambiguous Articulation of Recommendations
	External Review
	Updating

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Lower Extremity Arterial Revascularization–Post-Therapy Imaging

Variant 1: Previous infrainguinal endovascular therapy or bypass. Asymptomatic. Surveillance.

Procedure	Appropriateness Category	Relative Radiation Level
US duplex Doppler lower extremity	Usually Appropriate	0
CTA lower extremity with IV contrast	Usually Not Appropriate	
MRA lower extremity without and with IV contrast	Usually Not Appropriate	0
MRA lower extremity without IV contrast	Usually Not Appropriate	0
Arteriography lower extremity	Usually Not Appropriate	

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Previous infrainguinal endovascular therapy or bypass. Claudication or CLI. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US duplex Doppler lower extremity	Usually Appropriate	0
CTA lower extremity with IV contrast	Usually Appropriate	☢ ☢ ☢
MRA lower extremity without and with IV contrast	Usually Appropriate	0
Arteriography lower extremity	May Be Appropriate	☢ ☢
MRA lower extremity without IV contrast	May Be Appropriate	0

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Previous infrainguinal endovascular therapy or bypass, presenting with cold, painful extremity and diminished pulses (acute limb ischemia). Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Arteriography lower extremity	Usually Appropriate	☢ ☢
CTA lower extremity with IV contrast	Usually Appropriate	☢ ☢ ☢
US duplex Doppler lower extremity	Usually Appropriate	0
MRA lower extremity without and with IV contrast	May Be Appropriate (Disagreement)	0
MRA lower extremity without IV contrast	May Be Appropriate	0

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Lower extremity peripheral arterial disease (PAD), defined as an ankle-brachial index (ABI) measurement ≤ 0.90 , affects >8 million people in the United States alone. Approximately 9% to 23% of patients older than age 55 are believed to suffer from the condition, of which more than 40% are asymptomatic. The principal cause of PAD is atherosclerosis, and thus risk factors for PAD closely parallel those for atherosclerosis elsewhere in the body (e.g., smoking, diabetes, hypertension, hyperlipidemia, family history, postmenopausal state, hyperhomocysteinemia, etc.). Patients with PAD are at an increased risk for cardiovascular death and all-cause mortality. PAD may present as claudication, ischemic rest pain, nonhealing ulcers, or gangrene; without treatment, many patients will go on to require some degree of amputation ranging from loss of one or more digits to major limb loss (below-knee or above-knee amputation).

Over the past several decades, a paradigm shift away from surgical treatment and toward endovascular therapy for PAD has occurred, with many now advocating surgical treatments only after one or more failed endovascular revascularization attempts. The BASIL trial demonstrated that patients with critical limb ischemia (CLI) presenting with rest pain, ulceration, and gangrene of the leg due to infrainguinal disease had similar amputation-free survival and quality-of-life outcomes whether they were randomized to a surgery-first or angioplasty-first treatment strategy. Furthermore, first-year costs associated with bypass surgery were about one-third higher than those associated with angioplasty. The long-term outcomes following surgical and endovascular therapy in the setting of CLI are the subject of the ongoing BEST-CLI trial, which has an estimated primary endpoint completion date in December 2018.

Whether endovascular or surgical revascularization is used, restenosis is a pervasive issue. As target lesion restenosis and adjacent segment disease typically precede frank occlusion and CLI, surveillance has been advocated for many years in the setting of bypass, and there is increasing evidence to support its use following angioplasty and stenting. Additionally, there has been a steady increase in the

investigative tools available to the vascular specialist to diagnose and stratify lesions in the lower extremity arteries. Because of the plethora of testing options available, it can be difficult for physicians to determine the most appropriate test to obtain in the setting of recurrent symptoms after therapy.

Overview of Imaging Modalities

Noninvasive Hemodynamic Testing

Noninvasive testing (NIVT), both before and after intervention, has been used for decades as a first-line investigatory tool in the diagnosis and categorization of PAD. It is widely available and provides a large amount of information at low cost without the use of ionizing radiation. NIVT can consist of one or more of the following components: the ABI, segmental pressure measurements (SPMs), pulse-volume recordings (PVRs), photoplethysmography (PPG), and transcutaneous oxygen pressure measurement (TcPO₂).

The ABI is defined as the ratio between the higher of the brachial artery pressures and the higher of the dorsalis pedis or posterior tibial artery pressures in each leg at the level of the ankle. The ABI is performed after 10 minutes of rest in the supine position for the most reliable and accurate measurement. An ABI between 0.9 and 1.31 is normal; measurements <0.9 are suggestive of PAD, while values >1.3 indicate noncompressible vessels (frequently present in patients with longstanding diabetes mellitus and chronic renal insufficiency). The toe-brachial index (TBI) has been shown to provide a more accurate estimation of the presence of PAD in these subgroups, with a TBI ≤0.7 considered abnormal. A major strength of ABI is the ability to simulate real-world conditions through the use of pre- and post-exercise determinations; a drop in ABI of 0.15 or more is suggestive of at least moderate arterial occlusive disease, even if the resting ABI is in the normal range. The ABI is limited in its usefulness, as it does not allow for the localization of disease, distinction between single level and multilevel disease, or the characterization of arterial occlusive lesions.

SPMs compare systolic pressures at sequential levels in the extremities to evaluate for significant drops between one level and the next. A pressure drop of ≥20 mmHg between adjacent measurements suggests one or more hemodynamically significant stenoses between them. SPMs allow the reader to distinguish the approximate level of disease, although the precise severity and number of lesions cannot be determined. Similar to the ABI, SPMs are limited in patients with noncompressible vessels.

PVRs provide a qualitative (rather than quantitative) measurement of limb perfusion. PVRs are created by inflating pneumoplethysmography cuffs to a specified pressure at predetermined levels on each limb. Each cuff measures the miniscule change in the volume of the limb under the cuff with each pulse, creating a tracing of volume versus time. The resultant waveforms can be compared to determine segmental disease, providing insight into the quality of arterial blood flow at each station simultaneously. PVRs are also useful in patients with noncompressible vessels, as this modality relies on limb volume change rather than the pressure required impeding flow through the vessel being interrogated.

PPG involves the detection of a transmitted infrared signal through each of the digits. The degree of transmitted signal varies depending on blood volume within the digit, blood vessel wall movement, and the orientation of red blood cells. PPG is useful for detection of disease below the knee as well as disease isolated to the forefoot and digits. As such, it has been demonstrated to be a complementary test to ABI, which has limited use in these segments.

TcPO₂ measurement allows the determination of the oxygen tension within tissue. An improvement in the TcPO₂ value postintervention compared with preintervention has been validated as an excellent marker of tissue reperfusion. TcPO₂ values >40 mmHg in the area surrounding the ulcer or amputation site are considered predictive of successful healing. This test is not limited by noncompressible vessels, and, in patients without pedal Doppler signals, it is one of the few NIVTs that is helpful. The test is limited by its availability in the office setting, patient resistance to avoiding smoking and caffeine prior to the test, as well as the time and cost constraints associated with providing the temperature-controlled

environment required to standardize the test.

US

Peripheral duplex ultrasound (DUS) imaging, which consists of grayscale 2-D imaging, color Doppler, and spectral waveform analysis, has been a mainstay of vascular imaging for decades. This technology is widely available, portable, does not require contrast agents, and can be used in the angiography suite or operating room. DUS has been validated as a screening tool, a first-line study for clinically suspected PAD, and as a tool to plan the approach for both endovascular and surgical intervention. In most situations, it is complimentary to NIVT, such as the ABI. US has a high sensitivity for the detection of patent tibial arteries but is less accurate in detecting complete occlusions, particularly in the peroneal artery. DUS has also been used to quantify the firmness of occlusions to determine the degree of chronicity to some success.

More recently, DUS has become a tool in the follow-up of prior endovascular interventions. Several papers recommend DUS as the first-line study following lower-extremity angioplasty. If initial follow-up is normal, further surveillance has been shown to be essentially no better than clinical follow-up and NIVT alone. However, in patients with persistent or recurrent disease seen on the initial study, a more aggressive surveillance program every 2 to 3 months is often warranted. Duplex has been validated for follow-up of prior angioplasty, stenting, and covered stenting/stent grafting but is of less utility in surveillance below the knee. Several papers argue toward immediate postintervention duplex as a "new baseline," often identifying lesions not identified angiographically, which may require more aggressive follow-up. Systolic velocity ratios ≥ 2.5 correlate well with symptom recurrence. When planning interventions, the anticipated intervention based on US alone was unchanged after angiogram in femoropopliteal and iliac lesions in $>80\%$ of patients, but only 59% in lesions below the knee. In critical limbs, close surveillance shows significant improvement in limb salvage rates over clinical follow-up alone.

Unfortunately, of all the noninvasive imaging techniques, US is also the most operator dependent and time consuming. The DIPAD trial, which evaluates the cost-benefit ratio of DUS compared with computed tomography angiography (CTA) and contrast-enhanced magnetic resonance angiography (CE-MRA), showed that although the initial cost of US is lower, this does not take into account the time-related expense and operator experience required to produce satisfactory imaging. Additionally, practitioner confidence in the results is often lower than with the more advanced techniques, leading to a greater number of follow-up studies prior to intervention.

CTA

Modern CTA has been demonstrated to be comparable to the gold standard (catheter-based angiography) for the detection of hemodynamically significant stenoses ($>50\%$) with sensitivity, specificity, and accuracy of 99%, 98%, and 98%, respectively. Refinements in CT protocols have also compared favorably to MRA with no statistically significant difference between the two modalities in the evaluation of claudication or CLI. Arterial opacification is significantly improved by using high-density compact contrast boluses, which is rapidly becoming the standard of care with equivalent iodine dose to previous standard bolus technique.

Potential drawbacks of CTA include the exposure to ionizing radiation and the use of iodinated contrast, which presents the potential for allergic reaction or contrast-induced nephropathy, particularly in those patients who already possess some degree of renal impairment. Metallic streak artifact is often problematic in patients with postsurgical changes or implanted hardware. Additionally, in extremely obese patients, the signal-to-noise ratio becomes somewhat prohibitive. Evaluation of densely calcified vessels can be difficult with CTA because of the similar density between plaque and contrast and the blooming artifact created by the former, leading to overestimation of the degree of stenosis in many cases, as well as the inability to determine patency in stented vessels. Because of the density of calcified plaque in relation to the relatively small lumen of the tibial vessels, CTA has traditionally suffered in the infrageniculate distribution.

Multiple studies have now validated dual-energy CTA as a practical and effective method for subtraction of calcified plaque and soft tissues, allowing for simultaneous creation of conventional CTA data sets and angiogram-like composite images of the vasculature alone. These subtraction images have been demonstrated to be nearly equivalent in diagnostic accuracy to those of conventional angiograms, with similar or less radiation using newer protocols. This technique has been improved at some institutions by subtracting the extravascular tissues in multiple segments rather than the entire study at once. Relatively recent advances in CTA technology include the use of dynamic (time-resolved) imaging of the tibial arteries, selective ultra-low-dose intra-arterial contrast-enhanced CTA, and CO₂-enhanced high-pitch CTA, all of which show promise in certain circumstances.

MRA

MRA has been used for many years in patients with PAD for both treatment planning and assessment of procedural success. Continued evolution of this technology and imaging protocols has improved image quality and increased the potential applications. Most MRA protocols provide both source images with excellent soft-tissue differentiation and subtracted images demonstrating the vasculature in 2-D and 3-D representations similar to those provided during conventional angiography.

In the current era, the accuracy of CTA and CE-MRA for the detection of hemodynamically significant PAD has become essentially equivalent, with an edge for CTA in the aortoiliac segment and for MRA in the infrageniculate distribution. In diabetics, MRA is considered particularly helpful for runoff evaluation because of its superior ability to detect flow in small, calcified vessels, approaching the sensitivity of digital subtraction angiography (DSA).

Venous contamination tends to decrease diagnostic accuracy, particularly in the runoff distribution. In the past, cuff compression had been used to increase venous pressure and therefore delay filling of the outflow, improving arterial opacification and diagnostic confidence. Reliance on this technique has decreased in recent years through advances in time-resolved techniques, so called "4-D MRA." This method allows evaluation of flow into a segment of tissue over time, simulating conventional angiography and allowing readers to select the time point at which each segment is optimally opacified. This technique increases sensitivity, specificity, and accuracy for PAD in all segments of the lower extremity arteries, but most importantly below the knee. Time-resolved imaging of the whole limb has also been reported. MRA provides imaging quality similar to DSA for the evaluation of lower extremity bypass conduits. It also allows for excellent evaluation of previously angioplastied segments and has a high specificity for in-stent patency; however, sensitivity for occlusion is still poor because of blooming artifact, particularly in stainless steel stents. Newer generation nitinol stents are less affected by this limitation.

There are several important limitations of MRA. Patients with most types of defibrillators, spinal cord stimulators, intracerebral shunts, cochlear implants, and other devices are excluded, as are patients affected by claustrophobia that is not overcome by sedation. Open-field 1.0T MRA has been used for claustrophobic patients, with imaging quality approaching that of DSA above the knee; however, below the knee, the technology is still quite limited. It takes longer to acquire images with MRA than with CTA, and the studies themselves are considerably more expensive. However, with MRA, patients are not exposed to ionizing radiation, and the risk of nephrotoxicity from gadolinium-based contrast is considerably less than that of iodinated contrast agents.

For a time, CE-MRA was considered an alternative to CTA in patients with renal impairment; however, since the association between renal failure and nephrogenic systemic fibrosis after gadolinium administration was discovered, it fell out of favor. This led to copious research of noncontrast MRA. Time-of-flight imaging is one such method, which, with current technology, provides images with equivalent accuracy to CE-MRA for popliteal and runoff assessment, but still lags behind in the aortoiliac and femoral segments. It is less expensive than CE-MRA, and has been proposed as a potential PAD screening test. Quiescent-interval single-shot MRA and flow-spoiled fresh-blood imaging are newer techniques, which may show promise in combination with conventional time-of-flight techniques. Quiescent-interval single-shot currently provides similar imaging quality and diagnostic accuracy to CE-MRA in runoff vessels of

diabetics, suggesting that perhaps a combination of noncontrast MRA techniques may provide equivalent whole-body vascular imaging to those provided by CE-MRA.

Many newer techniques in MRA show excellent promise in certain circumstances. Perfusion imaging using arterial spin labeling has been used to quantify arterial flow in the thigh and calf musculature, which has been shown to have equal or greater sensitivity for PAD compared with ABI, independent of the amount of preimaging exercise time. Arterial peak flow velocity measurements can be obtained using phase-contrast techniques, comparing well to those obtained using spectral Doppler. The vessel wall itself can be evaluated using blood-suppression, allowing for quantification and characterization of plaque and restenosis. Continuous table movement MRA is a newer method that promises similar imaging quality to conventional multi-station MRA, with 30% faster imaging acquisition.

Arteriography

DSA is the reference standard to which CTA and MRA are compared. DSA can localize and quantify obstructive lesions, permits physiological evaluation by the determination of pressure gradients, and allows for intervention at the time of diagnosis. In high-acuity settings, such as a thrombosed bypass graft, where immediate catheter-based intervention is likely to be indicated, direct referral to catheter angiography is a valid option. However, DSA is an invasive technique with a small but definite risk in every patient. Access-site hematoma, arterial dissection, thrombosis, and limb loss are known complications that can result from the procedure and occur in up to 2.0% of patients in this population. These occur less frequently with increasing operator experience. For this document, it is assumed the procedure is performed and interpreted by an expert. Serious systemic complications are also possible, with increased risk in patients with severe widespread vascular disease, diabetes, renal insufficiency, or other contraindications to the use of iodinated contrast media. Carbon dioxide angiography may be of value in these patients. In light of the risk of nephrogenic systemic fibrosis in patients with severe renal disease, gadolinium chelates serve a very limited role as DSA contrast agents. Although DSA remains the gold standard for diagnosing PAD at the time of intervention, it generally plays no role in the surveillance of arterial segments previously treated with endovascular methods and in grafts without clinical evidence of malfunction.

Discussion of Procedures by Variant

Variant 1: Previous Infrainguinal Endovascular Therapy or Bypass. Asymptomatic. Surveillance

The most important indicator of restenosis or occlusion in the setting of previous revascularization is recurrence of symptoms. There is limited data to suggest that treatment of asymptomatic patients after endovascular therapy provides any long-term benefit. As such, patients presenting to the clinic for follow-up of previous endovascular therapy or bypass for PAD should be evaluated for symptoms of claudication and rest pain, and should be examined closely for evidence of lower extremity ulceration or gangrene. ABI should be determined at each follow-up visit in all previously treated patients with PAD. PVRs can provide insight into subtle changes in arterial flow quality between segments, often preceding detectable anatomic changes on other modalities; however, they are fraught with reader subjectivity, poor patient cooperation, and baseline abnormalities in poor cardiac output. A recent paper has also called into question whether they provide any benefit over ABIs and SPMs alone.

US

DUS demonstrates a high correlation between elevated PSV at sites of previous treatment and recurrence of symptoms, although this argues that symptoms alone could be used to determine recurrent disease. Following endovascular therapy, DUS is indicated for an initial follow-up, but several studies have found no benefit in repeated US in the absence of an abnormality on the initial examination. US surveillance of lower extremity bypass grafts (both vein grafts and synthetic) has been commonplace since the 1980s, when it was determined that a PSV within a graft of <40 to 45 cm/s was consistent with a graft at risk of failure. An end-diastolic velocity ≤ 5 cm/s at the conclusion of a bypass procedure is a strong predictor of early graft occlusion. Poor compliance with bypass surveillance has been demonstrated as an independent risk factor for acute graft thrombosis. This is particularly true of vein grafts, which are more likely to

develop a stenosis prior to occlusion than a synthetic graft, which often occludes without warning. Duplex has been shown to be more useful in the evaluation of femorotibial than femoropopliteal grafts. DUS speckle tracking has been used to detect early neointimal hyperplasia in vein grafts prior to anatomically detectable stenosis. However, several other authors have found no significant change in disease endpoints for vein grafts with surveillance. One study found that primary-assisted patency was "significantly" higher in patients undergoing surveillance than those only followed clinically; however, the margin of benefit was relatively minimal. Another paper suggested that >10% of patients with a detectable graft stenosis on initial imaging will occlude in the next 3 to 6 months.

MRA

Although both CE-MRA and nonenhanced MRA have been proposed as potential screening tests for PAD, particularly in patients in whom NIVT is limited (i.e., diabetics) and time constraints remain prohibitive, there is no convincing evidence in the literature arguing for the use of CE-MRA or nonenhanced MRA for surveillance of previously treated PAD, either with endovascular or surgical methods. False positives suggesting recurrent disease in asymptomatic patients could lead to unnecessary procedures.

CTA

Because of availability, the use of ionizing radiation and the risks inherent to iodinated contrast, CTA is not recommended for routine follow-up of asymptomatic patients with nonaneurysmal PAD.

Arteriography

As an invasive test, lower extremity arteriography is completely inappropriate for surveillance of asymptomatic patients. There is no evidence to support its use in this setting.

Variant 2: Previous Infrainguinal Endovascular Therapy or Bypass. Claudication or CLI. Initial Imaging

NIVT is an ideal first test to evaluate patients presenting with symptoms of lower extremity arterial insufficiency. NIVT allows rapid delineation between vascular and neurogenic or musculoskeletal causes of lower extremity pain, as well as determining the likelihood of an ischemic component of ulcerations. A significant drawback of these tests is the inability to determine whether the previously treated segment or a new segment is the cause for the patient's symptoms, although comparison between the abnormal segment on NIVT and previous imaging can provide some insight. TBI, PVR, and TcPO₂ determinations are of particular use in diabetic patients, in which the ABI and SPM are often misleading. Should some degree of amputation be required, TcPO₂ measurements have been shown to help guide the highest necessary level of tissue removal by predicting the likelihood of postsurgical healing. Although these tests allow determination of the likely cause of the patient's symptoms, they are of relatively little use in procedural planning, particularly for patients where previous angiography or cross-sectional imaging is not available.

US

DUS has a very high correlation with clinical deterioration after both endovascular therapy and bypass for lower-extremity PAD. Following angioplasty, DUS has been validated as accurate for determining the specific levels of hemodynamically significant disease, although it often underestimates the extent of disease beyond the first significant stenosis. The aortoiliac segment can be evaluated in some patients, although obesity and bowel gas artifact are a pervasive problem. In combination with spectral Doppler, inflow disease can often be excluded and can guide the interventional approach (i.e., retrograde contralateral versus antegrade ipsilateral access). Duplex is valuable in the determination of flow within and beyond stented and stent-grafted segments, and is slightly less limited than CTA and MRA, particularly in smaller-caliber stents. The identification and treatment of symptomatic restenosis associated with a previously treated segment has been shown to provide improved long-term outcomes and patency in both endovascular and surgical patients. In many cases, patients can proceed directly to intervention with Duplex arterial mapping alone. In the setting of bypass, Duplex can determine whether the graft is patent, threatened, or occluded, and often can identify specific segments of disease to guide either endovascular repair or surgical revision.

MRA

MRA provides excellent-quality imaging of all arterial segments approaching that of DSA even in the tibial vessels, particularly when combined with time-resolved methods. In the hands of an experienced operator, DUS can provide detailed arterial maps prior to intervention; however, in the setting of multi-segmental disease, it can become difficult to determine the patient's TransAtlantic Inter-Society Consensus classification, which often guides decision making between endovascular and surgical treatments. For this document, it is assumed the procedure is performed and interpreted by an expert. MRA carries a Level 1A recommendation for MRA from the American College of Cardiology/American Heart Association (ACC/AHA) for the definition of the precise anatomic relationships of arterial stenotic lesions; however, it is subject to overestimation of the degree of stenosis. This suggests that it is best used in combination with tests that provide insight into the hemodynamic significance of lesions, such as NIVT and DUS. MRA can be used effectively to guide therapy in patients who have undergone both a previous angioplasty with or without stenting as well as patients with bypass grafts. MRA can decrease procedure times, radiation and contrast doses, and can provide better assessment of risk and the likelihood of procedural success prior to undergoing intervention.

Although nonenhanced MRA can provide imaging quality and diagnostic confidence levels similar to that from CE-MRA, protocols and image quality vary significantly between institutions. Additionally, the lack of time-resolved imaging limits evaluation in the infrageniculate segment. Its use is generally reserved for patients who require evaluation of suspected aortoiliac and femoropopliteal lesions in the setting of renal insufficiency. The use of this modality is likely to evolve over the next decade given the vast amount of research in this area over the past few years.

CTA

In the era of modern CTA, vascular imaging quality is similar to that of DSA, albeit with a modest limitation in the infrageniculate distribution due to contrast-timing issues and the frequency of tibial calcification. Through the acquisition of isotropic voxels on new scanners, images can be reconstructed in any plane, including curved planar reformats along the lumen of the vessel. Particularly suited for aortoiliac and femoropopliteal evaluation, CTA is an excellent choice for the evaluation of claudicants, in which tibial disease is both less frequently present and less frequently treated. Similar to MRA, it is best suited in combination with tests providing data on the hemodynamic significance of identified lesions (NIVT and DUS).

Arteriography

Given the similar sensitivity and specificity of MRA and CTA compared with DSA, this invasive modality is generally reserved for immediate pretreatment evaluation of PAD and is rarely used solely for diagnostic purposes. The ability to acquire pressure measurements can help determine whether a previously identified stenosis is truly hemodynamically significant, which can sometimes be difficult to determine with NIVT and DUS in the setting of multilevel disease. It is occasionally used to determine surgical targets for infrageniculate bypass in patients with densely calcified runoff vessels who are deemed to be poor endovascular candidates, although noninvasive cross-sectional imaging has essentially replaced angiography for this indication as well.

Variant 3: Previous Infrainguinal Endovascular Therapy or Bypass, Presenting with Cold, Painful Extremity and Diminished Pulses (Acute Limb Ischemia). Initial Imaging

Physical examination is critical in suspected acute limb ischemia/threatened limb, which is, at its core, a clinical diagnosis. The temperature and appearance of the limb, absence of palpable pulses or arterial signals by Doppler, loss of sensation, and decreased or absent strength in the affected extremity all provide insight into the urgency of the event. There is little evidence regarding the use of imaging in the setting of a threatened limb, and no tests should be performed that would significantly delay therapy in a patient with impending limb loss. Patients with severe ischemia, as indicated by motor loss or severe sensory deficits (Rutherford class IIb or III), should likely proceed directly to definitive therapy, usually surgical thromboembolectomy or bypass. Although a full spectrum of NIVT may be too time consuming in

an acutely threatened limb, the determination of the ABI and SPM can assist in the determination of both the etiology of the symptoms and can also guide the level of necessary intervention.

US

DUS may provide the ability to determine whether the patient has an acute event associated with a previously treated segment or not. Brief evaluation of the venous system can also exclude other potential causes for acute lower extremity ischemia, such as phlegmasia cerulea dolens. Limited US evaluation for the evaluation of bilateral common femoral patency, the determination of inflow quality, and the patency of lower extremity bypass conduits can help guide expeditious treatment. Given portability and ubiquity in the hospital system, this can potentially be performed by physicians in the emergency department to triage patients to appropriate vascular specialists. For this document, it is assumed the procedure is performed and interpreted by an expert. There is increasing focus on training vascular specialists to perform point-of-care DUS to quickly determine the etiology and extent of limb ischemia during the initial consultation. This is particularly true for bypass conduits, which are generally located superficially and easily assessed sonographically. However, these tests should not delay definitive therapy if it is immediately available.

Arteriography

Immediately threatened limbs (Rutherford class IIb and early presentations of class III) require rapid definitive therapy, and generally should proceed directly to emergency thromboembolectomy to prevent limb loss. In the setting of viable or marginally threatened limbs (Rutherford class I or IIa), immediate arteriography for the evaluation of anatomic relationships between diseased segments is the preferred procedure. Angiography provides detailed and accurate information regarding the etiology and extent of the insult that has caused acute limb ischemia and may allow a catheter-based treatment in some patients. This can allow patients to be appropriately triaged to either surgery or endovascular therapy, the latter of which may involve thrombolysis or percutaneous thrombectomy, angioplasty, stenting, etc. If performed without prior NIVT or US, there is the potential for longer procedure times, increased contrast use and possibly multiple access sites to provide definitive therapy.

CTA

In patients with acute limb ischemia and viable or marginally threatened limbs, CTA may be considered for preprocedural evaluation given its near-equivalent accuracy compared to diagnostic angiography. CTA is a rapid modality that can provide insight into the precise location of vessel occlusion, and in some centers it is supplanting arteriography as the test of choice prior to intervention. It is particularly useful in patients who present with bilateral symptoms where inflow disease is suspected. However, its use should not delay definitive therapy. Additionally, the use of iodinated contrast agent for this modality can limit the ability to provide subsequent angiographic therapy because of the risk of contrast-induced nephropathy.

MRA

MRA is a time-consuming procedure, and its use in patients with acute limb ischemia should be reserved for those in whom motor and sensory function are preserved and the determination between endovascular and surgical therapy remains obscure. There are no studies to date independently comparing MRA with CTA or angiography in this patient population; however, given the length of the procedure, it is likely not an appropriate test in patients who require revascularization emergently (i.e., within the next 3–6 hours), such as patients with Rutherford IIb or III ALI.

Similar to CE-MRA, nonenhanced MRA is time consuming and should only be used in patients with renal insufficiency where the determination between endovascular and surgical therapy remains obscure.

Summary of Recommendations

The combination of longitudinal clinical evaluation and comparisons of noninvasive hemodynamic testing, particularly the ABI, provides a large degree of information and can appropriately frame the

patient's presentation.

In patients who are asymptomatic post revascularization, DUS is the mainstay examination given the high correlation between abnormal findings and recurrence of symptoms. Initial post-treatment DUS can determine a baseline for future follow-up.

In patients presenting with claudication or chronic limb ischemia post revascularization, noninvasive hemodynamic testing in combination with DUS and CTA or contrast-enhanced MRA can guide therapy in patients who have undergone both a previous angioplasty with or without stenting, as well as patients with bypass grafts.

In patients presenting with symptoms of acute limb ischemia, time is of the essence, particularly if motor and sensory deficits are noted and redundant examinations should not delay definitive therapy. DUS, CTA, and arteriography are all rapid examinations that can delineate the level of acute abnormality and help guide treatment.

Abbreviations

CLI, critical limb ischemia

CTA, computed tomographic angiography

IV, intravenous

MRA, magnetic resonance angiography

US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
0	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢ ☢	0.1-1 mSv	0.03-0.3 mSv
☢ ☢ ☢	1-10 mSv	0.3-3 mSv
☢ ☢ ☢ ☢	10-30 mSv	3-10 mSv
☢ ☢ ☢ ☢ ☢	30-100 mSv	10-30 mSv

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Lower extremity peripheral arterial disease (PAD)

Guideline Category

Evaluation

Management

Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Radiology

Intended Users

Advanced Practice Nurses

Health Care Providers

Hospitals

Managed Care Organizations

Physician Assistants

Physicians

Students

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of imaging procedures for imaging after lower extremity arterial revascularization

Target Population

Patients who have had lower extremity arterial revascularization

Interventions and Practices Considered

- Ultrasound (US), duplex Doppler, lower extremity
- Computed tomography angiography (CTA), lower extremity with intravenous (IV) contrast
- Magnetic resonance angiography, lower extremity
 - With and without IV contrast
 - Without IV contrast
- Arteriography, lower extremity

Major Outcomes Considered

- Utility of imaging procedures in imaging after lower extremity arterial revascularization
- Sensitivity, specificity, and accuracy of imaging procedures after lower extremity arterial revascularization

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Summary

Literature searches were conducted in July 2015 and August 2017 to identify evidence for the *ACR Appropriateness Criteria® Lower Extremity Arterial Revascularization–Post-Therapy Imaging* topic. Using the search strategy described in the literature search companion (see the "Availability of Companion Documents" field), 532 articles were found. Fifty-nine articles were used in the topic. The remaining articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, or the results were unclear, misinterpreted, or biased.

The author added 29 citations from bibliographies, Web sites, or books that were not found in the literature search, including 26 articles outside of the search date ranges.

One citation is a supporting document that was added by staff.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

Number of Source Documents

The literature searches conducted in July 2015 and August 2017 found 59 articles that were used in the topic. The author added 29 citations from bibliographies, Web sites, or books that were not found in the literature search, including 26 articles outside of the search date ranges. One citation is a supporting document that was added by staff.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Definitions of Study Quality Categories

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - The study has important study design limitations.

Category 4 - The study or source is not useful as primary evidence. The article may not be a clinical study, the study design is invalid, or conclusions are based on expert consensus.

The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);

Or

The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;

Or

The study is an expert opinion or consensus document.

Category M - Meta-analysis studies are not rated for study quality using the study element method because the method is designed to evaluate individual studies only. An "M" for the study quality will indicate that the study quality has not been evaluated for the meta-analysis study.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Overview

The purpose of the rating rounds is to systematically and transparently determine the panels' recommendations while mitigating any undue influence of one or more panel members on another individual panel members' interpretation of the evidence. The panel member's rating is determined by reviewing the evidence presented in the Summary of Literature Review and assessing the risks or harms of performing the procedure or treatment balanced with the benefits of performing the procedure or treatment. The individual panel member ratings are used to calculate the median rating, which determines the panel's rating. The assessment of the amount of deviation of individual ratings from the panel rating determines whether there is disagreement among the panel about the rating.

The process used in the rating rounds is a modified Delphi method based on the methodology described in the RAND/UCLA Appropriateness Method User Manual.

The appropriateness is rated on an ordinal scale that uses integers from 1 to 9 grouped into three categories (see the "Rating Scheme for the Strength of the Recommendations" field).

Determining the Panel's Recommendation

Ratings represent an individual's assessment of the risks and benefits of performing a specific procedure for a specific clinical scenario on an ordinal scale. The recommendation is the appropriateness category (i.e., "Usually appropriate", "May be appropriate", or "Usually not appropriate").

The appropriateness category for a procedure and clinical scenario is determined by the panel's median rating without disagreement (see below for definition of disagreement). The panel's median rating is calculated after each rating round. If there is disagreement after the second rating round, the rating category is "May be appropriate (Disagreement)" with a rating of "5" so users understand the group disagreed on the final recommendation. The actual panel median rating is documented to provide additional context.

Disagreement is defined as excessive dispersion of the individual ratings from the group (in this case, an Appropriateness Criteria [AC] panel) median as determined by comparison of the interpercentile range (IPR) and the interpercentile range adjusted for symmetry (IPRAS). In those instances when the IPR is greater than the IPRAS, there is disagreement. For a complete discussion, please refer to chapter 8 of the RAND/UCLA Appropriateness Method User Manual.

Once the final recommendations have been determined, the panel reviews the document. If two thirds of the panel feel a final recommendation is wrong (e.g., does not accurately reflect the evidence, may negatively impact patient health, has unintended consequences that may harm health care, etc.) and the process must be started again from the beginning.

For additional information on the ratings process see the Rating Round Information document (see the "Availability of Companion Documents" field).

Additional methodology documents, including a more detailed explanation of the complete topic development process and all ACR AC topics can be found on the [ACR Web site](#) (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Cost Analysis

The DIPAD trial, which evaluates the cost-benefit ratio of peripheral duplex ultrasound (DUS) compared with computed tomography angiography (CTA) and contrast-enhanced magnetic resonance angiography (CE-MRA), showed that although the initial cost of ultrasound (US) is lower, this does not take into account the time-related expense and operator experience required to produce satisfactory imaging.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current medical evidence literature and the application of the RAND/UCLA appropriateness method and expert panel consensus.

Summary of Evidence

Of the 89 references cited in the ACR Appropriateness Criteria® Lower Extremity Arterial Revascularization–Post-Therapy Imaging document, 16 are categorized as therapeutic references including 1 well-designed study, 9 good-quality studies, and 2 quality studies that may have design limitations. Additionally, 68 references are categorized as diagnostic references, including 5 well-designed studies, 13 good-quality studies, and 24 quality studies that may have design limitations. There are 30 references that may not be useful as primary evidence. There are 5 references that are meta-analysis studies.

Although there are references that report on studies with design limitations, 28 well-designed or good-quality studies provide good evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- With magnetic resonance angiography (MRA), patients are not exposed to ionizing radiation, and the risk of nephrotoxicity from gadolinium-based contrast is considerably less than that of iodinated contrast agents.
- MRA can decrease procedure times, radiation and contrast doses, and can provide better assessment of risk and the likelihood of procedural success prior to undergoing intervention.
- One study found that primary-assisted patency was "significantly" higher in patients undergoing surveillance with ultrasound than those only followed clinically; however, the margin of benefit was relatively minimal. In critical limbs, close surveillance shows significant improvement in limb salvage rates over clinical follow-up alone.
- The identification and treatment of symptomatic restenosis associated with a previously treated segment has been shown to provide improved long-term outcomes and patency in both endovascular and surgical patients.

Potential Harms

- False positives of magnetic resonance angiography (MRA) suggesting recurrent disease in asymptomatic patients could lead to unnecessary procedures.

- Serious systemic complications are possible with arteriography, with increased risk in patients with severe widespread vascular disease, diabetes, renal insufficiency, or other contraindications to the use of iodinated contrast media.
- Unfortunately, of all the noninvasive imaging techniques, ultrasound (US) is also the most operator dependent and time consuming. Practitioner confidence in the results is often lower than with the more advanced techniques, leading to a greater number of follow-up studies prior to intervention.
- Potential drawbacks of computed tomography angiography (CTA) include the exposure to ionizing radiation and the use of iodinated contrast, which presents the potential for allergic reaction or contrast-induced nephropathy, particularly in those patients who already possess some degree of renal impairment. Metallic streak artifact is often problematic in patients with postsurgical changes or implanted hardware. Additionally, in extremely obese patients, the signal-to-noise ratio becomes somewhat prohibitive. Evaluation of densely calcified vessels can be difficult with CTA because of the similar density between plaque and contrast and the blooming artifact created by the former, leading to overestimation of the degree of stenosis in many cases, as well as the inability to determine patency in stented vessels. Because of the density of calcified plaque in relation to the relatively small lumen of the tibial vessels, CTA has traditionally suffered in the infrageniculate distribution

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Contraindications

Contraindications

Patients with most types of defibrillators, spinal cord stimulators, intracerebral shunts, cochlear implants, and other devices are excluded from receiving magnetic resonance angiography (MRA), as are patients affected by claustrophobia that is not overcome by sedation.

Qualifying Statements

Qualifying Statements

- The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate

other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

- ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Cooper K, Majdalany BS, Kalva SP, Chandra A, Collins JD, Francois CJ, Ganguli S, Gornik HL, Kendi AT, Khaja MS, Minocha J, Norton PT, Obara P, Reis SP, Sutphin PD, Rybicki FJ, Expert Panel on Vascular Imaging. ACR Appropriateness Criteria® lower extremity arterial revascularization—post-therapy imaging. Reston (VA): American College of Radiology (ACR); 2017. 14 p. [89 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

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2017

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

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The funding for the process is assumed entirely by the American College of Radiology (ACR). ACR staff support the expert panels through the conduct of literature searches, acquisition of scientific articles, drafting of evidence tables, dissemination of materials for the Delphi process, collation of results, conference calls, document processing, and general assistance to the panelists.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Vascular Imaging

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Disclosing Potential Conflicts of Interest and Management of Conflicts of Interest

An important aspect of committee operations is the disclosure and management of potential conflicts of interest. In 2016, the American College of Radiology (ACR) began an organization-wide review of its conflict of interest (COI) policies. The current ACR COI policy is available on its [Web site](#) . The Appropriateness Criteria (AC) program's COI process varies from the organization's current policy to accommodate the requirements for qualified provider-led entities as designated by the Centers for Medicare and Medicaid Services' Appropriate Use Criteria (AUC) program.

When physicians become participants in the AC program, welcome letters are sent to inform them of their panel roles and responsibilities, including a link to complete the [COI form](#) . The COI form requires disclosure of all potential conflicts of interest. ACR staff oversees the COI evaluation process, coordinating with review panels consisting of ACR staff and members, who determine when there is a conflict of interest and what action, if any, is appropriate. In addition to making the information publicly available, management may include exclusion from some topic processes, exclusion from a topic, or exclusion from the panel.

Besides potential COI disclosure, AC staff begins every committee call with the conflict of interest disclosure statement listed below reminding members to update their COI forms. If any updates to their COI information have not been submitted, they are instructed not to participate in discussion where an undisclosed conflict may exist.

Finally, all ACR AC are published as part of the Journal of the American College of Radiology (JACR) electronic supplement. Those who participated on the document and are listed as authors must complete the JACR process that includes completing the International Committee of Medical Journal Editors (ICMJE) COI form which is reviewed by the journal's staff/publisher.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [American College of Radiology \(ACR\) Web site](#) .

Availability of Companion Documents

The following are available:

ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2017.

Available from the [American College of Radiology \(ACR\) Web site](#) .

ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb. 1 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria®. Evidence table development. Reston (VA): American College of Radiology; 2015 Nov. 5 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria®. Topic development process. Reston (VA): American College of Radiology; 2015 Nov. 2 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria®. Rating round information. Reston (VA): American College of Radiology; 2017 Sep. 5 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2017. 4 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 2017. 125 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2017 Mar. 4 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria® lower extremity arterial revascularization–post-therapy imaging. Evidence table. Reston (VA): American College of Radiology; 2017. 39 p. Available from the [ACR Web site](#) .

ACR Appropriateness Criteria® lower extremity arterial revascularization–post-therapy imaging. Literature search. Reston (VA): American College of Radiology; 2017. 2 p. Available from the [ACR Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on March 15, 2018. The guideline developer agreed to not review the content.

This NEATS assessment was completed by ECRI Institute on February 14, 2018. The information was verified by the guideline developer on March 15, 2018.

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